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DG Health and Consumer Protection (SANCO)-Unit 3 European Commission B-1049 Brussels Belgium

Brussels, 24 March 2011

Dear

Please find enclosed the Application (without the updating statement) for approval renewal for glyphosate and the IPA-, K- and NH4 salts of glyphosate by Monsanto Europe S.A. on behalf of the Glyphosate Task Force (GTF).

Since the Pre-Submission meeting with the Rapporteur Member State (Germany), the dimethyl amine (DMA) salt has been evaluated by at least one member state and there is a pending registration which is expected to be granted in the next few weeks. Consequently, Dow AgroSciences requested to add it as an "existing salt" in the Application and Updating Statement. The guidance given at the Pre-Submission meeting was that existing salts should be dealt under AIR2, but new salts should be evaluated in the standard formulated product registration process.

It is not clear if the DMA should be considered "existing" or "new", depending whether it is the evaluation or the registration which triggers the decision. Guidance is awaited from the BVL. Until that time, the Glyphosate Task Force wishes to make the Commission aware that the evaluation of this salt may be required in addition to the IPA, ammonium and potassium salts.

If it is considered to be an existing salt, then the GTF will simply provide the required information on identity and three studies on physico-chemical properties to be added to the List of new and existing studies.

Yours sincerely,		

APPLICATION FOR APPROVAL RENEWAL

Glyphosate & the IPA-,K- and NH₄-salts of Glyphosate

RMS: Germany
Co-RMS: Slovakia

APPLICATION

Notifier(s): Monsanto Europe SA on behalf of the 'Glyphosate Task Force' Date: March 24, 2011

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ANNEX 2 — LETTER FROM THE GLYPHOSATE TASK FORCE EXPRESSING AN INTENTION TO RENEW THE APPROVAL OF GLYPHOSATE90

1 Information concerning the applicant

1.1	Name and address of the applicant including the name of the natural person responsible for the	
	application and further engagements resulting from this Regulation:	

Monsanto Europe N.V./S.A.

Haven 627

Scheldelaan 460

B-2040 Antwerp

Belgium

Applying on behalf of the members of the <u>European Glyphosate Task Force</u>¹. The membership of this task force is further detailed in Addendum-1 to this application and is updated upon change of membership on: <u>www.glyphosatetaskforce.org</u>.

1.2.1

- (a) Telephone No: +32
- (b) Fax No: +32
- (c) E-mail address:

@monsanto.com

1.2.2

(a) Contact:

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Document ID: Application for approval renewal: glyphosate

Author:

¹ The European Glyphosate Task Force is a consortium of companies joining resources and effort s in order to renew the European glyphosate registration; this consortium is not a legal entity.

2 Information to facilitate identification

2.1 Common name (proposed or ISO-accepted) specifying, where relevant, any variants thereof such as salts, esters or amines produced by the manufacturer:

Active ingredient:

Glyphosate

Related salt-types:

Glyphosate- isopropyl-amine-salt

Glyphosate-potassium-salt Glyphosate-ammonium-salt

2.2 Chemical name (IUPAC and CAS nomenclature):

Glyphosate:

IUPAC:

N-(phosphonomethyl)-glycine

CAS:

N-(phosphonomethyl)-glycine

Glyphosate- isopropyl-amine-salt:

IUPAC:

N-(phosphonomethyl)glycine - isopropylamine (1:1)

CAS:

N-(phosphonomethyl)glycine compound with 2-propanamine (1:1)

Glyphosate-potassium-salt:

IUPAC:

potassium N-[(hydroxyphosphinato)methyl]glycine

CAS:

N-(phosphonomethyl) glycine potassium salt (1:1)

Glyphosate-ammonium-salt:

IUPAC:

ammonium N-[(hydroxyphosphinato)methyl]glycine

CAS

N-(phosphonomethyl)glycine mono-ammonium salt

2.3 CAS, CIPAC and EEC numbers (if available):

Glyphosate

CAS N°: 1071-83-6 CIPAC N°: 0284

EEC Nº: 213-997-4

Glyphosate isopropyl-amine-salt

CAS N°: 38641-94-0 CIPAC N°: 284.105 EEC N°: 254-056-8

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Glyphosate potassium-salt

CAS N°: 70901-20-1 CIPAC N°: 284.019 EEC N°: not attributed

Glyphosate ammonium-salt

CAS N°: 40465-66-5 CIPAC N°:284.007 EEC N°: not attributed

2.4 Empirical and structural formula, molecular mass:

Glyphosate

Empirical formula: C3H8NO5P

Structural formula:

Molecular mass: 169.1 g/mol

Glyphosate isopropyl-amine-salt:

Empirical formula: C₆H₁₇N₂O₅P

Structural formula:

$$\begin{bmatrix} -O & CH_2 & + CH_2 & OH \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & \\ & & & \\ & &$$

Molecular mass: 228.18 g/mol

Glyphosate potassium-salt

Empirical formula: C3H7KNO5P

Structural formula:

$$\begin{bmatrix} -O & CH_2 & + CH_2 & OH \\ N & N & O \end{bmatrix} K^+$$

Molecular mass: 207.19 g/mol

Glyphosate ammonium-salt

Empirical formula: C₃H₁₁N₂O₅P

Structural formula:

$$\left[\begin{array}{c|c} -O & CH_2 & + CH_2 & P & OH \\ \hline & N & H & H & O \end{array}\right] \stackrel{+}{N}H_4$$

Molecular mass: 186.10 g/mol

2.5 Specification of purity of the active substance in g/kg which should be whenever possible identical or already accepted as equivalent to the one included in Annex I to Directive 91/414/EEC.

Minimum purity: 950 g/kg

2.6 Classification and labelling of the active substance in accordance with the provisions of Regulation (EC) No 1272/2008 of the European Parliament and Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures² (health and environment effects).

Glyphosate:

Classification	Hazard statement codes	Pictogram, Signal word codes
Eye damage 1	H318	GHS05
Aquatic chronic 2	H411	GHS09
		Danger

Salts of Glyphosate (with the exception of those specified elsewhere in Annex IV of Regulation (EC) No 1272/2008) NOTE: glyphosate trimesium is currently the only exception and is not part of this application):

Classification	Hazard statement codes	Pictogram, Signal word
Aquatic chronic 2	H411	GHS09

An updating statement, as provided for in Article 5(2), shall be attached as an Annex to the application. The applicant confirms that the above information submitted on March 25, 2011 is correct.

Signature (of the person competent to act for the applicant referred to under 1.1)

Document ID: Ap	plication for	approval	renewal:	glyphosate
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ADDENDUM 1: Glyphosate Task Force Membership (status 24/3/2011)

The membership of this task force is kept updated on: www.glyphosatetaskforce.org.

In alphabetical order:

Agrichem B.V.

Koopvaardijweg 9 4906 CV Oosterhout NB The Netherlands

Industrias Afrasa S.A.

C/Ciudad de Sevilla N°53. Pol.Ind.Fuente del Jarro 46988 Paterna (Valencia) Spain

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Ireland

Thyborønvej 78

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Italia

Excel Industries (Europe) NV

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Belgium

Feinchemie Schwebda GmbH

Edmund Rumpler Straße 6 51149 Köln

Germany

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Nordkanalstrasse 28

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Haven 627, Scheldelaan 460 B-2040 Antwerp Belgium

Nufarm GmbH & Co KG

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Société Financière de Pontarlier

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Syngenta Crop Protection AG

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Switzerland

United Phosphorus Ltd

Chadwick House, Birchwood Park Warrington, WA3 6AE, United Kingdom

Wynca UK Limited

32 Threadneedle Street, London, EC2R 8AY United Kingdom

The following companies have asked to be included in this application although they <u>are not members of the Task</u> Force. They have applied to join the Task Force and their applications are not yet complete:

AGRO TRADE GmbH

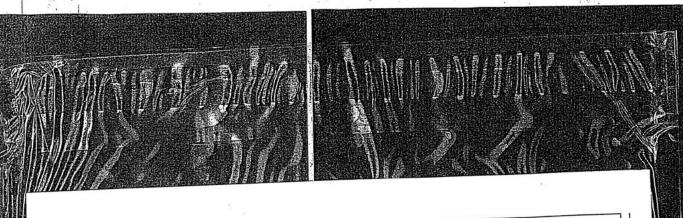
Baerweiler Strasse 55 55568 Lauschied Germany

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Bros Spolka Jawna B.P. Miranowscy

ul. Sokola nr 7, lok. 6 60 - 644 Poznan Poland



1 KG

PAK

1 OF 2

MONSAN 10 TERVURENLAAN 270-270 1150 BRUSSEL

SHP#: 2386 VZVD 8NN

SHP WT: 1 KG SHP DWT: 1 KG DATE: 25 MAR 2011

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Receipt&PrinterID=SVMyOD...

EUROPEAN COMMISSION

DG HEALTH AND CONSUMER PROTECTION RUE FROISSART 101

1049 BRUSSELS



BEL 344 9-00



UPS EXPRESS

TRACKING #: 1Z 238 6V2 66 9721 9618



BILLING: P/P

EDI

Reference No.1:

WXPIESO 12.0A 01/2011

standarional shinments crassing customs harders are required to have supporting documentation for customs cleatance. Pouch for Commercial Invoices/Shipping Documentation

HIER VOUWEN